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GIBBS, TERRA C	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,442	TANG ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed December 12, 2006.

Claims 5, 8-10, 15, and 16 have been amended.

Claims 1-29 are pending in the instant application.

Claims 1-29 are subject to restriction as detailed below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said SARS virus, classifiable in class 536, subclass 24.5, for example. **If this Group is elected, a further restriction is required as detailed below.**

II. Claims 6-10, drawn to a method of detecting a SARS virus in a sample comprising (a) contacting RNA obtained from said sample with a gene specific primer comprising a 3' region that is complementary to a SARS sequence and a 5' sequence that is not

complementary to a SARS sequence and synthesizing a first strand cDNA molecule by RT followed by (b) amplifying said first stand cDNA in a PCR using a pair of primers, wherein the first primer is complementary to said 5' region and wherein the second primer comprises a sequence in the SARS genome that is upstream of the region recognized by said 3' region, and (c) detecting the product of said PCR, classifiable in class 435, subclass 6, for example. **If this Group is elected, a further restriction is required as detailed below.**

III. Claims 11-29, drawn to a method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus, classifiable in class 514, subclass 44, for example. **If this Group is elected, a further restriction is required as detailed below.**

The inventions are distinct, each from the other, because of the following reasons:

Group I is related to Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said SARS virus of Group I can be used in materially different process such as a hybridization probe in a method of identifying SARS gene expression *in situ*, which is a materially different process than the method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus of Group III. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions

require a different field of search (see MPEP 808.02). Therefore, restriction for examination purposes as indicated is proper.

Group II is drawn to a method of detecting a SARS virus in a sample comprising (a) contacting RNA obtained from said sample with a gene specific primer comprising a 3' region that is complementary to a SARS sequence and a 5' sequence that is not complementary to a SARS sequence and synthesizing a first strand cDNA molecule by RT followed by (b) amplifying said first stand cDNA in a PCR using a pair of primers, wherein the first primer is complementary to said 5' region and wherein the second primer comprises a sequence in the SARS genome that is upstream of the region recognized by said 3' region, and (c) detecting the product of said PCR, and is considered to be distinct from the method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus of Group III. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group II is distinct from the method of Group III because the

method of Group II recites distinct method steps, apart from the method steps recited in Group III. Furthermore, the method of Group II is distinct from the method of Group III since the invention of Group II does not overlap in scope with that of Group III since each Group set recites materially distinct materials. Because these independent Groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Furthermore, because these independent Groups utilize unique and different method steps, the prior art applicable to one Group would not likely be applicable to another Group and the inventions in each Group are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Accordingly, restriction between Groups II and III is considered proper.

If Group I is elected, claim 4 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants

regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 4 specifically claims an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said SARS virus, and wherein the said nucleotide sequence of a SARS virus is selected from a SARS nps1, nps9, or spike sequence. The instant nucleotide sequence of a SARS virus are considered to be unrelated, since each nucleotide sequence of a SARS virus is structurally and functionally independent and distinct for the following reasons: each nucleotide sequence of a SARS virus codes for an entirely different target gene (per Applicant's disclosure at page 21, lines 14-20). As such, the Markush/genus of nucleotide sequence of a SARS virus in claim 4 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the nucleotide sequence of a SARS virus claimed in claim 4 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed nucleotide sequence of a SARS virus. In view of the foregoing, **one** (1) nucleotide sequence of a

SARS virus is considered to be a reasonable number for examination purposes. Accordingly, if Group I is elected, Applicants are required to elect **one** (1) nucleotide sequence of a SARS virus from claim 4. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group I is elected, claim 5 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 5 specifically claims an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide

sequence of a SARS virus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a SARS virus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said SARS virus, wherein said first strand comprises a sequence selected from SEQ ID NO: 1-6. The instant first strand sequences are considered to be unrelated, since each first strand sequence claimed is structurally and functionally independent and distinct for the following reasons: each first strand sequence is composed of different nucleic acid sequences (per Applicant's claim 5). As such, the Markush/genus of first strand sequences in claim 5 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the first strand sequences claimed in claim 5 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed first strand sequences. In view of the foregoing, **one** (1) first strand sequence is considered to be a reasonable number for examination purposes. Accordingly, if Group I is elected, Applicants are required to elect **one** (1) first strand sequence from claim 5. It is noted that the elected first strand sequence from claim 5 must correspond to the elected nucleotide sequence of a SARS virus from claim 4. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group II is elected, claim 7 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE

MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 7 specifically claims a method of detecting a SARS virus in a sample comprising (a) contacting RNA obtained from said sample with a gene specific primer comprising a 3' region that is complementary to a SARS sequence and a 5' sequence that is not complementary to a SARS sequence and synthesizing a first strand cDNA molecule by RT followed by (b) amplifying said first stand cDNA in a PCR using a pair of primers, wherein the first primer is complementary to said 5' region and wherein the second primer comprises a sequence in the SARS genome that is upstream of the region recognized by said 3' region, and (c) detecting the product of said PCR, wherein the gene specific primer is complementary to a SARS nps1, nps9, or spike sequence.

The instant gene specific primers complementary to a sequence are considered to be unrelated, since each gene specific primer complementary to a sequence claimed is structurally and functionally independent and distinct for the following reasons: each gene specific primer is complementary to an entirely different target gene and each gene specific primer is composed of different nucleic acid sequences (per Applicant's disclosure at pages 21, lines 14-20; page 23, lines 5-28; and page 24, Table). As such, the Markush/genus of gene specific primer complementary to a sequence in claim 7 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the gene specific primers complementary to a sequence claimed in claim 7 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed gene specific primers complementary to a sequence. In view of the foregoing, **one** (1) gene specific primer complementary to a sequence is considered to be a reasonable number for examination purposes. Accordingly, if Group II is elected, Applicants are required to elect **one** (1) gene specific primer complementary to **one** (1) target sequence from claim 7. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group II is elected, claims 8-10 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim

can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 8-10 specifically claims a method of detecting a SARS virus in a sample comprising (a) contacting RNA obtained from said sample with a gene specific primer comprising a 3' region that is complementary to a SARS sequence and a 5' sequence that is not complementary to a SARS sequence and synthesizing a first strand cDNA molecule by RT followed by (b) amplifying said first stand cDNA in a PCR using a pair of primers, wherein the first primer is complementary to said 5' region and wherein the second primer comprises a sequence in the SARS genome that is upstream of the region recognized by said 3' region, and (c) detecting the product of said PCR, wherein said gene specific primers is selected from SEQ ID NOs. 7-10; and wherein said second primer is selected from SEQ ID NOs: 11-13. The instant gene specific primers are considered to be unrelated, since each gene specific primer claimed is structurally and

functionally independent and distinct for the following reasons: each gene specific primer is complementary to an entirely different target gene and each gene specific primer is composed of different nucleic acid sequences (per Applicant's disclosure at pages 21, lines 14-20; page 23, lines 5-28; and page 24, Table). As such, the Markush/genus of gene specific primers in claims 8-10 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the gene specific primers claimed in claims 8-10 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed gene specific primers. In view of the foregoing, **one** (1) gene specific primer is considered to be a reasonable number for examination purposes. Accordingly, if Group II is elected, Applicants are required to elect **one** (1) first gene specific primer from claims 8 and 9 and **one** (1) second gene specific primer from claim 10. It is noted that the elected gene specific primers elected from claims 8-10 must correspond to the elected gene specific primer complementary to **one** (1) target sequence from claim 7. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group III is elected, claims 15 and 29 are subject to an additional restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the

entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 15 and 29 specifically claims a method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus, wherein the coronavirus is a SARS virus, and wherein the said nucleotide sequence of a SARS virus is selected from a SARS nps1, nps9, or spike sequence. The instant nucleotide sequence of a SARS virus are considered to be unrelated, since each nucleotide sequence of a SARS virus is structurally and functionally independent and

distinct for the following reasons: each nucleotide sequence of a SARS virus codes for an entirely different target gene (per Applicant's disclosure at page 21, lines 14-20). As such, the Markush/genus of nucleotide sequence of a SARS virus in claims 15 and 29 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the nucleotide sequence of a SARS virus claimed in claim 15 and 29 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed nucleotide sequence of a SARS virus. In view of the foregoing, **one** (1) nucleotide sequence of a SARS virus is considered to be a reasonable number for examination purposes. Accordingly, if Group III is elected, Applicants are required to elect **one** (1) nucleotide sequence of a SARS virus from claims 15 and 29. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group III is elected, claim 16 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334

(CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 16 specifically claims a method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus, and wherein said first strand comprises a sequence selected from SEQ ID NO: 1-6. The instant first strand sequences are considered to be unrelated, since each first strand sequence claimed is structurally and functionally independent and distinct for the following reasons: each first strand sequence is composed of different nucleic acid sequences (per Applicant's claim 16). As such, the Markush/genus of first strand sequences in claim 16 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the first strand sequences claimed in claim 16 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more

than one (1) of the claimed first strand sequences. In view of the foregoing, **one** (1) first strand sequence is considered to be a reasonable number for examination purposes. Accordingly, if Group III is elected, Applicants are required to elect **one** (1) first strand sequence from claim 16. It is noted that the elected first strand sequence from claim 16 must correspond to the elected nucleotide sequence of a SARS virus from claim 15. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

If Group III is elected, claim 17 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 17 specifically claims a method of treating or preventing a coronavirus infection in a subject, comprising administering to said subject and effective amount of a composition comprising an isolated double stranded molecule comprising a first strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus and a second strand comprising a ribonucleotide sequence which corresponds to a nucleotide sequence of a coronavirus, wherein said double-stranded molecule inhibits expression of said nucleotide sequence of said coronavirus, and wherein the double-stranded RNA molecule comprises a sequence selected from SC2, SC5, SC14, and SC15. The instant double-stranded RNA sequences are considered to be unrelated, since each double-stranded RNA sequence claimed is structurally and functionally independent and distinct for the following reasons: each double-stranded RNA sequence is composed of different nucleic acid sequences (per Applicant's disclosure at Figure 9). As such, the Markush/genus of double-stranded RNA sequences in claim 17 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the double-stranded RNA sequences claimed in claim 17 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed double-stranded RNA sequences. In view of the foregoing, **one** (1) double-stranded RNA sequence is considered to be a reasonable number for examination purposes. Accordingly, if Group III is elected, Applicants are required to elect **one** (1) double-stranded RNA sequence from claim 17. It is noted that the elected double-stranded RNA sequence from claim 17 must

correspond to the elected nucleotide sequence of a SARS virus from claim 15. Note that this is not a species election but a restriction of distinct and independent inventions: unique and distinct nucleic acid sequences.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must

include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James “Doug” Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 10, 2008
/Terra Cotta Gibbs/

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/554,442	TANG ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	